C A N A D A

PROVINCE OF QUEBEC
DISTRICT OF MONTRÉAL

NO : 500-06- 000906 - 186

(Class Action)
SUPERIOR COURT

STEVEN VARNAI, domiciled at [redacted]

and

JOANNE GIROUX domiciled at [redacted]

Applicants

v.

JANSSEN INC., legal person duly constituted, having its principal place of business at 19 Green Belt Drive, North York, Ontario, M3C 1L9;

and

JANSSEN PHARMACEUTICALS INC., legal person duly constituted, having its principal place of business at 1125, Trenton Harbourton Road, Titusville, New Jersey, 08560;

and

JANSSEN ORTHO LLC., legal person duly constituted, having its principal place of business at Stateroad 933, Km 0.1, Street Gurabo, Puerto Rico, 00778;

and

JOHNSON & JOHNSON INC., legal person duly constituted, having its principal place of business at 88 McNabb Street, Markham, Ontario, L3R 5L2 and a

place of business at 7101, rue Notre-Dame Est, Montreal, province of Quebec, H1N 2G4;

and

JOHNSON & JOHNSON, legal person duly constituted, having its principal place of business at One Johnson & Johnson Plaza, New-Brunswick, New-Jersey, United States of America, 08933;

Defendants

APPLICATION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION AND TO APPOINT THE STATUS OF REPRESENTATIVES PLAINTIFFS
(Articles 571 C.C.P. and following)
(nd : 67-205/Invokana)

TO ONE OF THE HONOURABLE JUSTICES OF THE QUEBEC SUPERIOR COURT, SITTING IN AND FOR THE DISTRICT OF MONTREAL, THE APPLICANTS STATE AS FOLLOWS :

I. GENERAL PRESENTATION

A. THE CLASS ACTION

1. The Applicants wish to institute a class action on behalf of the following Class, of which they are Members (the "Class Members") :

> "All individuals residing in Quebec who have used canagliflozin marketed under the brand names Invokana or Invokamet; and
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> All individuals residing in Quebec, who suffered damages from the use of canagliflozin marketed under the brand names Invokana or Invokamet, by one of the persons concerned in the preceding paragraph; notably, their spouse, father, mother and other ascendants, their children, their legal mandataries, their close relatives, other relatives and/or their estate (hereinafter the "Class" or "Class Members"). "

or such other Class definition as may be approved by the Court.

2. Invokana and/or Invokamet are used in the treatment of patients with type 2 diabetes;

3. This action arises out of the Defendants' unlawful, negligent, inadequate, improper, unfair, and deceptive practices and misrepresentations related to their design, development, testing, research, manufacture, licensing, labelling, warning, marketing, distribution, and sale of Invokana and/or Invokamet;

4. The Defendants misrepresented that Invokana and/or Invokamet are safe and effective, when in fact it causes serious injuries and complications, as more fully described below;

5. The injuries and complications suffered due to Invokana and/or Invokamet include, but are not limited to increased risk of lower limb amputations, diabetic ketoacidosis, acute kidney injuries and the need for further surgeries;

6. The Applicants therefore accuse the Defendants for having allegedly designed, researched, tested, developed, manufactured, prepared, processed, inspected, packaged, labelled, sold, promoted, distributed and/or marketed Invokana and/or Invokamet, without duly warning them against the risks and dangers involved;

7. Due to the grievances and omissions of the Defendants, the Applicants and the Members of the proposed Class suffered damages for which they wish to claim compensation;

B. THE DEFENDANTS

Janssen

8. The Defendant Janssen Pharmaceuticals, Inc. is an American corporation, having its head office in Titusville, New Jersey;

9. Janssen Pharmaceuticals, Inc. is identified as the manufacturer for Invokana and Invokamet in the U.S.;

10. Janssen Pharmaceuticals, Inc. authors, publishes, and maintains the Invokana and Invokamet web sites, which are sources of information regarding the safety and efficacy of Invokana and/or Invokamet that are used by consumers worldwide, including in Quebec;

11. The Defendant Janssen Inc. is a Canadian corporation, having its head office in Don Mills, Ontario;

12. Janssen Inc. is the sponsor or market authorization holder for Invokana, meaning that it is the entity authorized by Health Canada to sell Invokana and/or Invokamet in Canada;

13. The Defendant Janssen Ortho LLC. is an American corporation, having its head office in Gurabo, Puerto Rico;

14. Janssen Pharmaceuticals, Inc., Janssen Inc. and Janssen Ortho LLC, shall hereinafter be collectively referred to as "**Janssen**";

15. Janssen designed, researched, developed, tested, manufactured, marketed, packaged, labeled, promoted, distributed, licensed, and sold Invokana and/or Invokamet for use throughout the world, including in Quebec;

Johnson & Johnson

16. The Defendant Johnson & Johnson is an American corporation, having its head office in New-Brunswick, New Jersey;

17. The Defendant Johnson & Johnson Inc., a wholly owned subsidiary of Johnson & Johnson, is a Canadian corporation, having its head office in Markham, Ontario;

18. Johnson & Johnson and Johnson & Johnson Inc., shall hereinafter be collectively referred to as "**J&J**";

19. J&J is a parent of Janssen;

20. Janssen and J&J shall hereinafter be collectively referred to as the "**Defendants**";

21. At all material times, the Defendants were engaged in the business of designing, manufacturing, developing, preparing, transforming, inspecting, researching, evaluating the conduct of clinical studies, the preparation of regulatory applications, the maintenance of regulatory records, the labelling, the marketing, promotional activities/and or the sale of Invokana and/or Invokamet, either directly or through an agent, subsidiary, representative or affiliate;

22. In view of the close relationship between the Defendants and the foregoing, each of the Defendants is severally liable for the acts and omissions of the others;

C) INVOKANA AND INVOKAMET

23. Canagliflozin (Invokana and Invokamet) is an orally administered SGLT-2 inhibitor produced by J&J and marketed in Canada, including in Quebec, by their subsidiary Janssen;

24. SGLT2 inhibitors lower blood sugar by causing the kidneys to remove sugar from the body through the urine;

25. According to Invokana's Product Monograph, Invokana can be used, along with diet and exercise, to improve blood sugar levels in individuals with type 2 diabetes;

26. It can also be used alone or with other diabetes treatments (including: metformin, sulfonylurea, metformin and pioglitazone, or with insulin);

27. Canagliflozin is available as a single-ingredient product under the brand name Invokana, and also in combination with the diabetes medicine metformin under the brand name Invokamet;

28. Invokana and Invokamet are both manufactured by Janssen Inc., which has a Canadian headquarters in Toronto, Ontario;

29. Invokana is available in 100 MG and 300 MG dosages. Invokana was first available in Canada in May of 2014;

30. Invokamet was first available in Canada in June 2016;

D) THE CAUSES OF ACTION – PRODUCT LIABILITY

1. OBLIGATIONS OF QUALITY AND SECURITY OF THE PRODUCT AND THE RISKS ASSOCIATED WITH INVOKANA

Increased risk of lower limb amputations

31. An approximately two-fold increased risk of lower limb amputations associated with canagliflozin use was observed in two large, randomized, placebo-controlled trials evaluating patients with type 2 diabetes who had either established cardiovascular disease or were at risk for cardiovascular disease;

32. These trials were CANVAS (Canagliflozin Cardiovascular Assessment Study) and CANVAS-R (A Study of the Effects of Canagliflozin on Renal Endpoints in Adult Participants With Type 2 Diabetes Mellitus);

33. Amputations of the toe and mid-foot were the most frequent (99 out of 140 patients with amputations receiving canagliflozin in the two trials);

34. However, amputations involving the leg, below and above the knee, were also observed (41 out of 140 patients with amputations receiving canagliflozin in the two trials);

35. Some patients had more than one amputation, some involving both limbs;

36. Lower limb infections, gangrene, diabetic foot ulcers, and ischemia were the most common precipitating medical events leading to an amputation;

37. On May 18, 2016, the FDA issued a Drug Safety Communication that interim clinical trial results found increased risk of leg and foot amputations, mostly affecting the toes, associated with canagliflozin, as it appears from a Safety announcement from the FDA, dated May 18, 2016, produced herein as **Exhibit P-1**;

38. In October 2016, the Product Monographs for Invokana and Invokamet were updated to include adverse reaction and consumer information discussing the risk of lower limb amputation based on interim results of the CANVAS study, as it appears from Invokana's July 2017 revised monograph, produced herein as **Exhibit P-2**;

39. On September 6, 2017, Health Canada issued a Dear Healthcare Professional Letter advising practitioners that an approximately two-fold increased risk of surgical lower limb amputation (primarily of the toe and midfoot but also of the leg) has been observed in two long-term clinical studies in type 2 diabetes patients with established cardiovascular disease (CVD) or at least two risk factors for CVD treated with Invokana, as it appears from a "recalls and safety alerts" document from Health Canada, dated September 6, 2017, produced herein as **Exhibit P-3**;

40. Health Canada is currently working with the manufacturer to update the Canadian Product Monographs regarding this safety information to reflect the final results of the CANVAS clinical trials;

Diabetic Ketoacidosis

41. On May 15, 2015, the FDA issued a warning about the risk of ketoacidosis with SGLT2 inhibitors, including Invokana, while they continued to evaluate the safety risk , as it appears from a Safety announcement from the FDA, dated May 15, 2015, produced herein as **Exhibit P-4** ;

42. The FDA Adverse Event Reporting System (FAERS) database from March 2013 to May 2015 identified 73 cases of ketoacidosis in patients with type 1 or type 2 diabetes treated with SGLT2 inhibitors;

43. FAERS includes only reports submitted to FDA, so there are likely additional cases about which we are unaware. All patients required hospitalization or treatment in an emergency department;

44. In many cases, ketoacidosis was not immediately recognized because the blood glucose levels were below those typically expected for diabetic ketoacidosis;

45. As a result, treatment of the ketoacidosis was delayed in some cases;

46. On December 4, 2015, the FDA issued a Safety Announcement that their safety review resulted in additional Warnings and Precautions to Invokana's label about the risk of

ketoacidosis;

47. The FDA also required manufacturers of SGLT2 inhibitors to conduct a postmarketing study;

48. This required enhanced pharmacovigilance study requests that manufacturers perform analyses of spontaneous postmarketing reports of ketoacidosis in patients treated with SGLT2 inhibitors, including specialized follow-up to collect additional information, for a period of 5 years, the whole as it appears from a Safety announcement from the FDA, dated December 4, 2015, produced herein as **Exhibit P-5**;

49. On May 16, 2016, Health Canada issued a Dear Healthcare Professional Letter warning that serious, sometimes life-threatening and fatal cases of diabetic ketoacidosis have been reported in patients SGLT2 inhibitors, as it appears from a "recalls and safety alerts" document from Health Canada, May 16, 2016, produced herein as **Exhibit P-6**;

50. The Canadian Product Monographs of these products were updated to reflect this safety information;

Acute kidney injury

51. A search of the FDA Adverse Event Reporting System (FAERS) database from March 29, 2013, to October 19, 2015, identified 101 cases of acute kidney injury with sufficient detail to confirm the diagnosis and demonstrate a temporal relationship with INVOKANA (canagliflozin);

52. Hospitalization for evaluation and management of acute kidney injury was necessary in 96 of the 101 cases, and 22 cases involved admission to an intensive care unit;

53. In October of 2015, Health Canada released a Summary Safety Review "Sodium Glucose Cotransporter 2 (SGLT2) Inhibitors INVOKANA (canagliflozin) and FORXIGA (dapagliflozin) - Evaluation of a Potential Risk of Acute Kidney Injury", as it appears from a Summary safety review document dated October 16, 2015, produced herein as **Exhibit P-7**;

54. Health Canada's safety review found a link between events of acute kidney injury and the use of INVOKANA (canagliflozin);

55. This issue was identified following new safety information received from the manufacturer of INVOKANA (canagliflozin) following the marketing of this product;

56. Health Canada required the manufacturers to update the Canadian prescribing information of INVOKANA (canagliflozin) to strengthen the wording relating to kidney injury to reflect this risk;

57. In June 2016, FDA required manufacturers of Invokana and Invokamet, to strengthen warnings on their drug labels to include an association with kidney failure soon after beginning to take the drug, as it appears from a Safety announcement from the FDA, dated June 14, 2016, produced herein as **Exhibit P-8**;

58. Excerpts from Health Canada's adverse effects registry show that at least one (1) amputation, seventy-five (75) kidney problems, two hundred (200) cases of Ketoacidosis and six (6) deaths were suspected to be linked to the use of Invokana or Invokamet, as it appears from the excerpts of Health Canada's adverse effects registry, produced herein as **Exhibit P-9**;

2. OBLIGATION OF INFORMATION ABOUT THE RISKS ASSOCIATED WITH INVOKANA AND/OR INVOKAMET

59. The Defendants, through their servants, agents and attorneys, failed to adequately warn physicians and consumers, including the Applicants and putative Class Members, of the risk of injuries and complications caused by Invokana and Invokamet;

60. The Defendants did not provide adequate safety data to the FDA or Health Canada with respect to Invokana and Invokamet;

61. The Defendants knew or ought to have known that Invokana and Invokamet were unsafe and that it caused serious injuries;

62. The Defendants, through their servants and agents, negligently, recklessly and carelessly marketed, distributed and/or sold Invokana and Invokamet without adequate warnings of the products' serious side effects and unreasonably dangerous risks associated with them;

E) FAULT

63. In any event, and without limiting the foregoing, the Defendants' conduct constitutes a misconduct liable under the *Civil Code of Quebec* and the *Consumer Protection Act*;

F) CAUSATION

64. The damages suffered by the Applicants and the Class Members are a direct and immediate consequence of the negligence of the Defendants, because they failed to ensure that canagliflozin (Invokana and Invokamet) was safe for the use for which it was intended and to provide adequate warnings of the risks associated with the use thereof;

65. The extent of the risk incurred was not known and could not have been known by the Applicants and the Members of the Class;

66. The Applicants' injuries would not have occurred if the Defendants hadn't failed to ensure that canagliflozin (Invokana and Invokamet) were safe for use, in the alternative, hadn't failed to provide an adequate warning of the risks associated with using canagliflozin (Invokana and Invokamet) to the Applicants, to Class Members and to their physicians;

G) DAMAGES

67. The injuries and damages sustained by the Applicants and Class Members were caused by the negligence of the Defendants, their agents and servants;

68. As a result of the Defendants' negligence, the Applicants and Class Members have suffered and continue to experience serious personal injuries and suffering;

69. As a result of faults and errors committed by the Defendants, the Applicants and Class Members have suffered and continue to suffer monetary losses and non-pecuniary losses, whose nature and amount will be determined by the Court;

70. The Applicants and Class Members also ask for punitive damages, given the illegal and reckless conduct of the Defendants;

II. FACTS GIVING RISE TO THE APPLICANTS CLAIM

The Applicant Steven Varnai

71. The Applicant, Steven Varnai, 63 years of age, is an individual residing in [redacted], in the province of Quebec;

72. In 2014, the Applicant was prescribed and used canagliflozin (Invokana) to manage his diabetes;

73. In December of 2015, he began feeling unwell, tired and short of breath;

74. He also developed a sore on his leg that was not healing;

75. On December 18, 2015, his wife took him to the Emergency Room of Lakeshore General Hospital to assess his shortness of breath;

76. At Lakeshore General Hospital, the Applicant learned that he had very severe heart complications, including reduced ejection fraction, and that he needed to be transferred

to Jewish General Hospital for treatment;

77. While undergoing cardiac care at Jewish General Hospital, the sore on his leg became infected and grew in size;

78. The Applicant's treating doctors were unable to control the infection and advised the Applicant that he required a left leg amputation below the knee;

79. As a result of the Applicant's cardiac complications and amputation, he was hospitalized for approximately 6 months, and subsequently completed extensive rehab.

80. The Applicant now walks with a prosthetic leg and has very limited mobility;

81. The Applicant stays home most days, and suffers from pain and mental distress over his situation;

82. Before his amputation, the Applicant owned and ran a deli;

83. As a result of the Applicant's health condition and mobility, he is unable to independently manage his business;

84. The Applicant, prior to being prescribed and taking Invokana, received no warning as to the extent of the risks of developing injuries and complications, resulting from Invokana;

85. Had the Applicant been aware of the extent of the risks of developing injuries and complications, he would never have agreed to use Invokana;

The Applicant Joanne Giroux

86. The Applicant, Joanne Giroux, 62 years of age, is an individual residing in [redacted] in the province of Quebec;

87. She is the spouse of the Applicant Steven Varnai and they have been married for 33 years;

88. Since her husband's injuries, she is responsible for all of the family errands and she runs the family business;

89. She has had to hire help with cleaning the house since she is now running the business;

90. She has to take her husband to all of his appointments and, thus, has spent a lot of money on parking between his time in the hospital, in rehab, and for follow up appointments;

91. All the damages suffered by her husband have had an adverse effect on their married

life and had a significantly impact on their quality of life;

92. In addition, her husband's health problems caused her significant emotional stress and major inconvenience;

93. As a consequence of the foregoing, the Applicant is entitled to claim compensation for moral, material and punitive damages she has suffered and continues to suffer;

94. As a consequence of the foregoing, the Applicants are entitled to claim compensation for physical, moral, material and punitive damages, for the damages they have suffered and continue to suffer;

III. FACTS GIVING RISE TO THE PERSONAL CLAIM OF EACH MEMBER OF THE CLASS

95. Each Member of the Class has purchased and ingested canagliflozin (Invokana or Invokamet) or is a close relative of the Member of the Class, who have taken it;

96. None of the Members of the Class has been notified sufficiently and in a timely manner by the Defendants, that the use of Invokana and/or Invokamet would expose them to serious risk of injury and complications, as described above;

97. Each Member of the Class shall be entitled to make a claim for damages for bodily, moral and material injuries suffered, as a result of the use of Invokana and/or Invokamet, as well as for punitive damages, if applicable;

IV. CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION

98. The composition of the Class makes it difficult or impracticable to apply the rules for mandates to take part in judicial proceedings on behalf of others or for consolidation of proceedings, with respect to provision 575 (3) of the *Code of civil procedure*, for the following reasons :

- The Applicants are unaware of how many persons throughout Quebec were using canagliflozin (Invokana and/or Invokamet);
- It is estimated that the number of people who can make up the Class are several hundred individuals;
- The Applicants do not know and cannot know the identity of the persons who have been using the use of Invokana and/or Invokamet, especially since medical and pharmaceutical files are confidential;

- The names and addresses of the persons composing the Class are unknown to the Applicants;

- It is difficult, if not impossible, to find each and every one of those involved in this action and to contact each member to obtain mandates to take part in judicial proceedings on behalf of others or for consolidation of proceedings;

99. The questions of fact and law raised by this action which are identical, similar or related and which relate to each Member of the Class to the Defendants and which the Applicants seek to resolve by this class action are :

- Does the use of canagliflozin (Invokana and/or Invokamet) cause severe injuries or complications, or does it increase the risk?

- Have the Defendants failed to comply with the following obligations, in particular under the *Consumer Protection Act* and the *Civil Code of Quebec* :

  - The obligation of quality and security in the use of canagliflozin (Invokana and/or Invokamet) increases the risks of suffering severe injuries and complications?

  - The obligation to inform Class Members enough, adequately and in a timely manner, about the risks associated with the use of canagliflozin (Invokana and/or Invokamet)?

- Did the Defendants otherwise engaged their civil liability?

- Are the Members of the Class entitled to claim a compensation for personal injury, moral and material damages, resulting from the use of the use of canagliflozin (Invokana and/or Invokamet)?

- Are members entitled to claim punitive and/or exemplary damages, if any?

100. The interests of justice weigh in favor of this motion being granted in accordance with its conclusions;

V. NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

101. The action that the Applicants wish to institute for the benefit of the Class Members is an action in damages based on product liability and from the professional seller;

102. The conclusions that the Applicants wish to introduce by way of an application to institute proceedings are :

GRANT the Applicants action against the Defendants;

GRANT the Applicants action on behalf of all the Members of the Class;

CONDEMN the Defendants severally to pay to Class Members:

- An amount up to a maximum of $ 500,000 to compensate for bodily, moral and/or material injuries for all members who used Invokana or Invokamet;
- An amount up to a maximum of $ 100,000 for all members who have suffered damages to someone close; including their spouse, father, mother and their parents, their children, their legal representatives, other relatives and/or their estate, as a result of the use of Invokana or Invokamet;
- Punitive damages, in an amount of $ 20 000 000;
- All costs and expenses related to the distribution of money to Members of the Class;

or such other amount as the Court may deem appropriate;

ORDER the treatment of individual claims of each Class Member in accordance with articles 599 to 601 C.C.P.;

THE WHOLE with the legal interest and the additional indemnity provided for in Article 1619 of the *Civil Code of Quebec* and with the full costs including the expenses of expert appraisals and all the expenses of publication of the notices to the members;

103. The Applicants suggest that this class action be exercised before the Superior Court in the District of Montreal for the following reasons :

- The Applicants reside in Montreal, in the judicial district of Montreal;
- The whole cause of action arose in the judicial district of Montreal, because :
  - The Applicant Steven Varnai was prescribed and used canagliflozin (Invokana) in Montreal;
  - The Applicants suffered damages in Montreal;
- Most members of the Class likely reside in the judicial district of Montreal or, more generally, in the appeal district of Montreal.

104. The Applicants, who seek to obtain the status of representatives, are able to adequately represent the Members of the Class, for the following reasons :

- The Applicant Steven Varnai was prescribed and used canagliflozin (Invokana);
- The Applicant Joanne Giroux is the spouse of the Applicant Steven Varnai;
- The Applicants suffered damages following the use of canagliflozin (Invokana);
- They understand the nature of the action;
- They contacted the undersigned lawyers and offered to act as Representatives in the context of the Class Action, in order to help people who are in a similar situation as they are; and
- They are available to dedicate the necessary time for an action and to collaborate with the Class Members.

105. The present motion is well-founded in fact and in law.

FOR THESE REASONS, MAY IT PLEASE THE COURT :

GRANT the present motion;

AUTHORIZE the bringing of a class action in the form of a motion to institute proceedings in damages;

ASCRIBE the Applicants the status of representatives of the persons included in the Class herein described as:

> "All individuals residing in Quebec who have used canagliflozin marketed under the brand names Invokana or Invokamet; and
>
> All individuals residing in Quebec, who suffered damages from the use of canagliflozin marketed under the brand names Invokana or Invokamet, by one of the persons concerned in the preceding paragraph; notably, their spouse, father, mother and other ascendants, their children, their legal mandataries, their close relatives, other relatives and/or their estate (hereinafter the "Class" or "Class Members"). "

or such other Class definition as may be approved by the Court.

IDENTIFY the principle questions of fact and law to be treated collectively as the following :

- Does the use of canagliflozin (Invokana and/or Invokamet) cause severe injuries or complications, or does it increase the risk?

- Have the Defendants failed to comply with the following obligations, in particular under the *Consumer Protection Act* and the *Civil Code of Quebec* :

  - The obligation of quality and security in the use of canagliflozin (Invokana and/or Invokamet) increases the risks of suffering severe injuries and complications?

  - The obligation to inform Class Members enough, adequately and in a timely manner, about the risks associated with the use of canagliflozin (Invokana and/or Invokamet)?

- Did the Defendants otherwise engaged their civil liability?

- Are the Members of the Class entitled to claim a compensation for personal injury, moral and material damages, resulting from the use of the use of canagliflozin (Invokana or Invokamet)?

- Are members entitled to claim punitive and/or exemplary damages, if any?

IDENTIFY the conclusions sought by the class action to be instituted as being the following :

GRANT the Applicants action against the Defendants;

GRANT the Applicants action on behalf of all the Members of the Class;

CONDEMN the Defendants severally to pay to Class Members :

- An amount up to a maximum of $ 500,000 to compensate for bodily, moral and/or material injuries for all members who used of Invokana or Invokamet;

- An amount up to a maximum of $ 100,000 for all members who have suffered damages to someone close; including their spouse, father, mother and their parents, their children, their legal representatives, other relatives and/or their estate, as a result of the use of Invokana or Invokamet;

- Punitive damages, in an amount of $ 20 000 000;

- All costs and expenses related to the distribution of money to Members of the Class;

or such other amount as the Court may deem appropriate;

ORDER the treatment of individual claims of each Class Member in accordance with articles 599 to 601 C.C.P.;

THE WHOLE with the legal interest and the additional indemnity provided for in article 1619 of the *Civil Code of Quebec* and with the full costs including the expenses of expert appraisals and all the expenses of publication of the notices to the members;

DECLARE that all Class Members that have not requested their exclusion from the Class in the prescribed delay will be bound by any judgement to be rendered on the class action to be instituted;

FIX the delay of exclusion at 30 days from the date of the publication of the notice to the Class Members;

ORDER the publication of a notice to the Members of the Class in the newspapers Journal de Montréal, Le Soleil and The Gazette, pursuant to section 591 C.C.P.

THE WHOLE with all legal costs, including expert fees and expenses for publication of the notices to the members.

Quebec, February 1st, 2018.

Siskinds, Desmeules

SISKINDS, DESMEULES, AVOCATS
(Me Karim Diallo)
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SUMMONS
(Articles 145 and following C.c.p.)

Filing of a judicial application

Take notice that the Applicants have filed this Application for Authorization to Institute a Class Action and to Appoint the Status of Representatives Applicants in the office of the Superior Court in the Judicial District of Montreal.

Defendants' answer

You must answer the Application in writing, personally or through a lawyer, at the courthouse of Montreal situated at 1, Notre-Dame Est street, Montreal, Quebec, H2Y 1B6, within 15 days of service of the Application or, if you have no domicile, residence or establishment in Quebec, within 30 days. The answer must be notified to the Applicants lawyer or, if the Applicants are not represented, to the Applicants.

Failure to answer

If you fail to answer within the time limit of 15 or 30 days, as applicable, a default judgement may be rendered against you without further notice and you may, according to the circumstances, be required to pay the legal costs.

Content of answer

In your answer, you must state your intention to:

- negotiate a settlement;
- propose mediation to resolve the dispute;
- defend the application and, in the case required by the Code, cooperate with the Applicants in preparing the case protocol that is to govern the conduct of the proceeding. The protocol must be filed with the court office in the district specified above within 45 days after service of the summons or, in family matters or if you have no domicile, residence or establishment in Quebec, within 3 months after service;
- propose a settlement conference.

The answer to the summons must include your contact information and, if you are represented by a lawyer, the lawyer's name and contact information.

Change of judicial district

You may ask the court to refer the originating Application to the district of your domicile or residence, or of your elected domicile or the district designated by an agreement with the Applicants.

If the Application pertains to an employment contract, consumer contract or insurance contract, or to the exercise of a hypothecary right on an immovable serving as your main residence, and if you are the employee, consumer, insured person, beneficiary of the insurance contract or hypothecary debtor, you may ask for a referral to the district of your domicile or residence or the district where the immovable is situated or the loss occurred. The request must be filed with the special clerk of the district of territorial jurisdiction after it has been notified to the other parties and to the office of the court already seized of the originating application.

Transfer of application to Small Claims Division

If you qualify to act as an Applicant under the rules governing the recovery of small claims, you may also contact the clerk of the court to request that the application be processed according to those rules. If you make this request, the Applicant's legal costs will not exceed those prescribed for the recovery of small claims.

Calling to a case management conference

Within 20 days after the case protocol mentioned above is files, the court may call you to a case management conference to ensure the orderly progress of the proceeding. Failing this, the protocol is presumed to be accepted.

Exhibits supporting the application

In support of the Application for Authorization to Institute a Class Action and to Appoint the Status of Representatives Applicants, the Applicants intend to use the following exhibits :

EXHIBIT P-1: Safety announcement from the FDA, dated May 18, 2016;

EXHIBIT P-2: Invokana's July 2017 revised monograph;

EXHIBIT P-3: "recalls and safety alerts" document from Health Canada, dated September 6, 2017;

EXHIBIT P-4: Safety announcement from the FDA, dated May 15, 2015;

EXHIBIT P-5: Safety announcement from the FDA, dated December 4, 2015;

EXHIBIT P-6: "recalls and safety alerts" document from Health Canada, dated May 16, 2016;

EXHIBIT P-7: Summary safety review document from Health Canada, dated October 16, 2015;

EXHIBIT P-8: Safety announcement from the FDA, dated June 14, 2016;

EXHIBIT P-9: Excerpts of Health Canada's adverse effects registry.

These exhibits are available on request.

Notice of presentation of an application

If the application is an application in the course of a proceeding or an application under Book III, V, excepting an application in family matters mentioned in article 409, or VI of the Code, the establishment of a case protocol is not required; however, the application must be accompanied by a notice stating the date and time it is to be presented.

Quebec, February 1st, 2018

Siskinds, Desmeules

SISKINDS, DESMEULES, AVOCATS
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C A N A D A
PROVINCE OF QUEBEC
DISTRICT OF QUEBEC

SUPERIOR COURT (CLASS ACTION)
NO :

STEVEN VARNAI ET AL.
Applicants

c.

JANSSEN INC.
et
JANSSEN PHARMACEUTICALS, INC.
et
JANSSEN ORTHO LLC
et
JOHNSON & JOHNSON INC.
et
JOHNSON & JOHNSON
Defendants

APPLICATION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION AND TO APPOINT THE STATUS OF REPRESENTATIVES PLAINTIFFS (Articles 571 C.C.P. and following), SUMMONS, LIST OF EXHIBITS

BB-6852 **Casier 15**

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